

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Mandro et al.	Attorney Docket:	1062/D78
Serial No.:	10/625,792	Art Unit:	2878
Filing Date:	July 23, 2003	Examiner:	Lee, P.J.
Invention:	OPTICAL DISPLACEMENT SENSOR FOR INFUSION DEVICES	Date:	June 5, 2007

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Response to Final Office Action of October 3, 2006**

Dear Sir:

In response to the Office Action dated October 3, 2006 and the new basis for rejection, Applicants submit a Request for Continued Examination and request further consideration of the application in view of the following amendments and remarks:

**The Claim Listing** begins on page 2 of this paper.

**Remarks** begin on page 5 of this paper.

## Claim Listing

1. (Previously Amended) A displacement sensor for a substance dispensing device having a translating piston, the sensor comprising:
  - a. a plunger rod coupled to the piston bearing an encoded pattern of encoding features, the spacing of the encoding features from one another defining spaces therebetween such that any two adjacent spaces form a unique sequence;
  - b. a light source for illuminating the encoded pattern;
  - c. a detector array for detecting light from the illuminated encoded pattern and generating a detector signal; and
  - d. a processor for determining a displacement of the plunger rod relative to a fiducial reference position based at least on the detector signal.
2. (Original) A displacement sensor according to claim 1, wherein the encoding features are regions of modulated optical transmission through the plunger rod.
3. (Original) A displacement sensor according to claim 1, wherein the encoding features are regions of modulated optical reflection by the plunger rod.
4. (Original) A displacement sensor according to claim 1, wherein the encoding features are a plurality of slots of enhanced transmission through the plunger rod.
5. (Original) A displacement sensor according to claim 4, wherein each slot is displaced from each pair of nearest neighbors by a unique combination of distances.
6. (Original) A displacement sensor according to claim 4, wherein the combination of any two adjacent spaces between slots uniquely identifies a characteristic of the reservoir.
7. (Original) A displacement sensor according to claim 6, wherein the identified characteristic of the reservoir is a displacement relative to a fiducial position.
8. (Original) A displacement sensor according to claim 6, wherein the identified characteristic of the reservoir is content of a reservoir to which the plunger rod pertains.
9. (Original) A displacement sensor according to claim 6, wherein the identified characteristic of the reservoir includes at least one of diameter and wall composition material.
10. (Original) A displacement sensor according to claim 1, wherein the light source includes an optical diffuser for illuminating a region of the plunger rod with substantially uniform optical intensity.

11. (Original) A displacement sensor according to claim 1, wherein the encoded pattern of encoding features repeats along the plunger rod.
12. (Previously Amended) A dispensing apparatus comprising:
  - a. a reservoir having a cylindrical inner volume for containing a substance;
  - b. a plunger rod for impelling a piston along a linear axis of motion within the inner volume of the reservoir in order to displace and dispense a measured quantity of the substance;
  - c. an encoding pattern of encoding features disposed along the plunger rod in a direction parallel to the linear axis of motion of the piston, the spacing of the encoding features from one another defining spaces therebetween such that any two adjacent spaces form a unique sequence;
  - d. an illumination source for illuminating the encoded pattern;
  - e. a detector array for detecting light from the illuminated encoded pattern and generating a detector signal; and
  - f. a processor for determining a displacement of the plunger rod relative to a fiducial reference position based at least on the detector signal.
13. (Original) A dispensing apparatus according to claim 12, wherein the encoding features are regions of modulated optical transmission through the plunger rod.
14. (Original) A dispensing apparatus according to claim 12, wherein the encoding features are a plurality of slots of enhanced transmission through the plunger rod.
15. (Original) A dispensing apparatus according to claim 14, wherein each slot is displaced from the pair of nearest neighbors by a unique combination of distances.
16. (Original) A dispensing apparatus according to claim 12, having more than 1 reservoir version, wherein the encoding pattern is uniquely determinative of a version of the reservoir.
17. (Previously Amended) A method for measuring a rate of dispensing a substance by means of a dispenser having a piston driven along an axis of motion within a reservoir of the substance, the method comprising:
  - a. illuminating with an illumination source an encoded pattern of encoding features disposed upon a plunger rod coupled to the piston, the spacing of the encoding features from one another defining spaces therebetween such that any two adjacent spaces form a unique sequence;

- b. detecting light from the illuminated encoding features and generating a detector signal; and;
  - c. determining a displacement of the plunger rod relative to a fiducial reference position based at least on the detector signal.
18. (Original) A method according to claim 17, wherein the step of detecting light further includes acquiring an image of the illuminated encoding features.
19. (Original) A method according to claim 17, wherein the step of determining a displacement further includes determining positions of peaks of light transmission through the encoding features.
20. (Original) A method according to claim 17, further including the step of storing each successive detector array value in each of successive groups of n software array elements.

## **REMARKS**

Claims 1-20 are currently pending in this application.

### **Objections**

Claims 1, 12 and 17 are objected to because the use of “therebetween” is inappropriate because it is not a word in the English dictionary.

The word "therebetween" is a valid English word in fact, the word "therebetween" is included in the claims of no less than 206,736 U.S. patents and in the specifications of no less than 400,994 U.S. patents issued between 1976 and the present (based on “quick” searches of the U.S. Patent Database).

Additionally, there are numerous places in the MPEP where the word "therebetween" is used, e.g., MPEP 806: "The general principles relating to distinctness or independence may be summarized as follows: (A) Where inventions are independent (i.e., no disclosed relation **therebetween**), restriction to one thereof is ordinarily proper..."

The Examiner is also invited to search for the word "therebetween" in the USPTO classification system (<http://www.uspto.gov/web/patents/classification/>). Numerous entries include the term "therebetween".

Thus, Applicants respectfully request withdrawal of the objection to the word “therebetween”.

### **35 U.S.C. § 103 (a) Rejections – Obviousness (Whatley et al. and Shearn)**

The Examiner rejects claims 1-20, stating they are unpatentable over US 6,452,158 to Whatley (hereinafter “Whatley” or “Whatley reference”) in view of US 6,645,177 to Shearn (hereinafter “Shearn” or “Shearn reference”). Specifically, the Examiner states the device disclosed in Whatley, combined with a modified Shearn, renders the Applicants’ invention obvious.

Applicants respectfully disagree. It would not be obvious to modify Shearn as suggested by the Examiner; the resultant device would not be functionally equivalent to Shearn.

The Shearn reference discloses a syringe driver system where one of the stem arms of the plunger is provided with a linear grid made up of a series of equally spaced markers along its length. See Shearn, col. 6, line 45-48. The distal markers are “smaller” whereas the markers at the proximal end are “larger”. See Shearn, col. 6, lines 48-52. These markers being both equally spaced as well as sized such that the markers are larger at the near end of infusion (NEOI) point and smaller elsewhere impart Shearn’s functionality.

The Shearn reference discloses the use of equally spaced markers, the majority of which are smaller markers, where each marker illuminates either one-detector or both-detectors. The markers are equally spaced and thus present equally spaced light and dark signals detected by the opto-electronics switch. The timing of these equally spaced signals can be used to confirm that the plunger is moving at the correct rate. See Shearn, col. 8, lines 21-24. Thus, the markers being equally spaced impart rate determination functionality.

Except for the larger marker closest to the distal end (i.e., the only larger marker immediately consecutive to a smaller marker, referred to herein as the “transitional marker”), each consecutive marker on the Shearn device is identical to and equally spaced from the previous marker. With respect to the transitional marker, the marker distal to the transitional marker is a smaller marker, but the marker proximal to the transitional marker is a larger marker. Thus, the Shearn device does not include “spacing of the encoding features defining spaces such that any two adjacent spaces form a unique sequence”. Quite the contrary, in fact, as the Shearn reference relies on the fact that all the markers are equally spaced for rate determination. If the Shearn reference were modified as suggested by the Examiner, the functionality of the Shearn detector (as stated in Shearn) would be destroyed.

If the Shearn reference were modified such that the spacing between the markers was different, the rate function of the equally spaced markers would be destroyed. As stated above, Shearn explicitly states that the “equally spaced dark and light signals are detected by the optoelectronics switch. The timing of these signals can be used by a control system to confirm that the plunger is moving at the correct rate”. See Shearn, col. 8, lines 21-24. The Examiner states the suggested modification would be obvious as a functional equivalent, however, as stated

above, the modification would destroy this functionality of the Shearn reference, thus, this can not be understood to be a functional equivalent.

Thus, to alter Shearn as suggested by the Examiner would negate Shearn functionality. Hence, it would not be obvious to one of ordinary skill in the art to modify Shearn as suggested by the Examiner, for the resultant Shearn device would not be functionally equivalent to the device disclosed in the Shearn reference. There would be no motivation by one of ordinary skill in the art to destroy functionality of the Shearn device.

Further, assuming the Shearn reference is modified such that the markers are all equal in length, however, the spacing between them were varied, in addition to destroying the rate determination functionality, this would also destroy the NEOI detection functionality of the Shearn detector. As explicitly stated and described in Shearn, the Shearn detector uses the larger markers to determine the NEOI:

“the markings on the arm at a near end of infusion (NEOI) point of the syringe have a first size and the markings elsewhere on the arm have a second size different than the first size such that the markings at the NEOI point allow illumination of a first number of the detectors and the markings elsewhere allow illumination of a second number of detectors different than the first number of detectors”.

See Shearn, col. 3, lines 65-67; col. 4, lines 1-5. Thus, were all the markers to be the same length (either the larger or smaller marker length) the signals would be exactly the same, thus, the NEOI, an explicitly stated advantage (See Shearn, col. 3, lines 5-6) of the Shearn detector, would never be detected. Additionally, were the markers random, i.e., smaller and larger markers dispersed randomly, the NEOI detection would not be possible as the signal at the proximal end would not be different from the signal elsewhere on the stem arm.

Therefore, modifying Shearn as suggested by the Examiner would not have been obvious to one of ordinary skill on the art as to do so would render Shearn non-functional.

Additionally, neither Whatley nor Shearn teach or otherwise suggest an encoded pattern of encoding features, wherein the spacing of the encoding features from one another define spaces therebetween such that any two adjacent spaces form a unique sequence, as required by the

claims. Among other things, such an encoded sequence provides for “fail-safe” operation in that the actual position of the plunger rod will not be mistaken for an erroneous position in the event detection of a mark is missed. Such fail-safe operation is simply not present in Whatley, whether or not combined with Shearn. Whatley’s pseudo-random code of equally spaced ‘1’s and ‘0’s is clearly not equivalent to the carefully designed encoding of the presently claimed invention because Whatley’s pseudo-random number sequences will have many non-unique repeats of binary number pairs (in fact, Whatley discloses a code element of “10101010” in FIG. 3). Shearn provides no suggestion or teaching to have any two adjacent spaces form a unique sequence. Furthermore, the Examiner argues that it would have been obvious to modify the teachings of Shearn such that the spaces between features are different, and while Applicants disagree, such argument misses the point because the claims do not merely require different spacing but instead require spacing such that any two adjacent spaces form a unique sequence. Thus, Applicants respectfully submit that the Examiner has failed to set forth a *prima facie* case of obviousness.

Thus, Applicants have shown that claims 1, 12 and 17 are not obvious over Whatley in view of Shearn, and as claims 1, 12, and 17 have been shown to be allowable, claims 2-11, 13-16 and 18-20 are allowable as being dependent on allowable base claims. Thus, Applicants respectfully request withdrawal of the rejection of claims 1-20 under 103(a).

### CONCLUSION

For at least the reasons detailed above, Applicants respectfully submit that all claims presently in the application are allowable over the art of record and early notice to that effect is respectfully solicited.

Applicants petition for a one month extension of time. In the event that a further extension is needed, this conditional petition of extension is hereby submitted. Applicants request that deposit account number 19-4972 be charged for any fees that may be required for the timely consideration of this application, including the fee for the Request for Continued Examination filed herewith and the fee for one month extension. Applicants believe that no additional fees are required; however, if any additional fees are required for the timely consideration of this application, please charge deposit account number 19-4972. The Examiner is requested to telephone the undersigned if any matters remain outstanding so that they may be resolved expeditiously.

Respectfully submitted,  
/Jeffrey T. Klayman, #39,250/

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Jeffrey T. Klayman  
Registration No. 39,250  
Attorney for Applicant

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BROMBERG & SUNSTEIN LLP  
125 Summer Street  
Boston, MA 02110-1618  
Tel: (617) 443-9292  
Fax: (617) 443-0004